SMALLPOX QUESTION AND ANSWERS

Smallpox Preparedness: Information to Support Public Health and Clinical Personnel Planning for Smallpox Vaccination

(Answers to questions received during and after broadcast "CDC Bioterrorism Update: Smallpox Preparedness," December 5-6, 2002)

NOTE: These questions and answers have been written for audiences (such as public health and healthcare professionals) who already have a basic understanding of smallpox and smallpox vaccination. Basic information for the general public can be found on the "Smallpox Basics" page (www.bt.cdc.gov/smallpox/basics).

IMPLEMENTATION

If all the medical volunteers in a small county have contraindications to receiving the vaccine, can the medical director designate non-clinical personnel?

Whether or not non-clinical personnel can be used in a vaccination clinic is dependent on state laws. Local health agencies should consult with their state health department on what is allowable.

Are nurses the only ones who can administer smallpox vaccine?

The vaccine can be administered by nurses, doctors, or other licensed healthcare professionals. Whether or not non-clinical personnel can be used in a vaccination clinic is dependent on state laws. Local health agencies should consult with their state health department on what is allowable.

For persons who recall having repeated smallpox vaccinations in childhood, none of which resulted in "takes," should they be allowed to volunteer for response teams? If in this current round of vaccinations they have two non-takes, should they be used on a smallpox response team?

People who failed to have a "take" as a child may have a take now and may still volunteer for response teams. If the volunteer still fails to demonstrate a "take" (after two attempts to vaccinate), they should not participate in the smallpox response team.

How do I find out who the BT grantee is for my state/area?

All the states, the District of Columbia, territories, and protectorates have been funded for bioterrorism activities. In addition, Chicago, Los Angeles County, and New York City have been funded. You can find contact information for state health agencies at www.cdc.gov/other.htm#states.

Since this is all part of bioterrorism preparedness, why aren't we also vaccinating against other bioterrorist agents?

There are a number of bioterrorism preparedness activities covering a wide range of activities and potential bioterrorist agents. The type of preparation varies among the different agents. Vaccination is a key part of smallpox preparedness.

If we end up with more volunteers than vaccine, how are we going to decide who gets it?
The state health departments will determine who will be offered vaccination as part of their smallpox preparedness plan. We have sufficient vaccine to cover potential vaccinees for stage 1 and stage 2 vaccination programs. We also have sufficient vaccine (as a diluted product) to vaccinate the entire country if need be, and more vaccine is being produced and tested.

Where can I find a listing of whom in hospitals should be getting smallpox vaccinations as part of this program?
A summary of the Advisory Committee on Immunization Practices (ACIP) meeting in which this was discussed can be found on this website in the document "Summary of October 2002 ACIP Smallpox Vaccination Recommendations."

Will reservists and National Guardsmen be receiving the vaccine?
Members of the National Guard (and reservists) would be included in the initial (stage 1) vaccination program if they were selected to be part of their state's public health response team or healthcare response team. They would be vaccinated through their state's vaccination program.

The legal questions are really hampering our program development. When can we expect more feedback on what liability protections exist for this program?
Liability issues are addressed in a "Smallpox Questions and Answers" document that has been prepared on Section 304 of the Homeland Security Act. You can find it on the CDC Smallpox website at www.bt.cdc.gov/agent/smallpox/vaccination/section-304-qa.asp.

Is there any need for people who have been vaccinated for smallpox as children to be vaccinated?
Yes. Smallpox vaccination provides high level immunity for 3 to 5 years and decreasing immunity thereafter. Someone who was vaccinated decades ago may retain some immunity but it is not known for certain that this level of immunity would protect them from smallpox. Now, the CDC is recommending that members of smallpox healthcare response teams who have not been vaccinated for smallpox in the past 3 years get the vaccine.

VACCINE DISTRIBUTION AND STORAGE

This is the first I've heard about smallpox vaccine being licensed. Is this a new vaccine?
No, this is the relicensing of the original calf lymph derived Dryvax® product from Wyeth-Ayerst.

I remember a smallpox vaccine "gun" many years ago. Will these be made available for clinics?
No. The vaccine will be administered with a bifurcated needle. This type of needle is very effective. It was used in the global smallpox eradication program.

What is the size of the individual vaccine kits?
Each vaccine kit will contain sufficient vaccine, diluent, and bifurcated needles to immunize 100 persons.

What is the size of the vaccine vial itself?
The vaccine vial will hold 100 doses of vaccine after reconstitution. The vial is about 1-1/2 inches tall and about 5/8 inches in diameter.

Other resources indicate different information on the storage and handling of smallpox vaccine. Which is correct?
Both unreconstituted and reconstituted vaccine should be stored at between 2 and 8 degrees C when not in use. It may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration. The vaccine is good for 30 days after being reconstituted and may be taken in and out of refrigeration as many times as needed during the course of those 30 days.

Is smallpox vaccine light sensitive?
The vaccine package insert does not indicate that the vaccine is light sensitive.

How do you suggest protecting the smallpox vaccine from light between vaccinations?
It is not necessary to protect the vaccine from light.

Can we aliquot the smallpox vaccine into smaller containers?
No. This would be a violation of the FDA licensure regarding the repacking of pharmaceutical supplies.

What do we do with the smallpox vaccine if we determine it has been frozen? If it hasn't been reconstituted, wouldn't it be okay?
You should contact the manufacturer for a determination.

How do we get these "holders" mentioned during the broadcast?
Stability holders will be shipped to you as part of the supplies provided by the National Pharmaceutical Stockpile.

Do we really need to use cardboard to separate the vaccine from the cold packs? We've always used paper.
Any inert substance may be used to separate the vaccine from the cold source. This may be corrugated cardboard, crumpled paper, styrofoam peanuts, etc.

If a clinic has concerns about the viability of vaccine, to whom can they speak?
They should contact the manufacturer, Wyeth.

I've seen a "safety bifurcated needle." Will this be provided through the CDC program?
No. Current kits have been created with standard bifurcated needles, the only needles approved by the FDA for administration of this vaccine.

Will bandage supplies be provided?
No. Vaccination sites are expected to provide bandage supplies.

Will waterproof bandages be provided?
No. Vaccination sites are expected to provide supplies.

What does the bifurcated needle look like?
The bifurcated needle is approximately 2-1/2 inches long with a very small two-pronged needle at one end. The prongs have a very small opening between them that holds the vaccine to be applied to the arm. The prongs are 1/16 inches long and are used to pierce the outer layer of the skin only. A photograph is available at www.bt.cdc.gov/agent/smallpox/images/hand_position_for_vaccination.jpg.

Is it possible to get extra bifurcated needles in addition to the number provided?
Vaccine kits will include 100 individually wrapped needles as part of the kit. Since each vial contains 100 doses of vaccine, this should be an adequate supply of needles. However, if a project area runs into problems, they should have their NPS coordinator contact the National Pharmaceutical Stockpile at the number provided in the shipping instructions.

Do we need to worry about maintaining the vaccine at a certain temperature while it's out during the vaccination clinic?
Normal ambient room temperature is acceptable.

When will new vaccine without antibiotics be available?
A vaccine for public use that does not contain antibiotics is currently undergoing licensing. No date for release is available at this time.

Is Dryvax® FDA-approved?
Yes. The Dryvax® vaccine being used for preparedness activities has been licensed by the FDA.

What are the guidelines for care and handling of the vaccine vial?
Both unreconstituted and reconstituted vaccine should be stored at between 2 and 8 degrees C when not in use. It may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration. The vaccine is good for 30 days after being reconstituted and may be taken in and out of refrigeration as many times as needed during the 30 day time frame.

Will CDC be shipping more than one type of vaccine to each site area? (Dryvax® and other newer vaccine) Will both be available to each site?
Only Dryvax® vaccine will be shipped for preparedness activities.

What is the origin of vaccinia virus?
The vaccinia virus is the "live virus" used in the smallpox vaccine. It is an orthopoxvirus related to smallpox. When given to humans as a vaccine, it helps the body to develop immunity to smallpox. The vaccinia virus may cause rash, fever, and head and body aches. In certain groups of people, complications from the vaccinia virus can be severe. The smallpox vaccines being distributed for this vaccination program contain the New York City Board of Health strain of live vaccinia virus (dried, calf lymph-type).

How is vaccinia vaccine manufactured?
Dryvax® was produced by Wyeth Lederle in the early 1980s from calf lymph containing live vaccinia virus. This vaccine is provided as a freeze-dried powder and contains the antibiotics polymyxin B, streptomycin, tetracycline, and neomycin. The diluent used to reconstitute the vaccine is 50 percent glycerin with a small amount of phenol as a preservative.

How long can reconstituted smallpox vaccine be stored?
Properly reconstituted and maintained Dryvax® vaccine can be stored and used for 30 days after being reconstituted. During that time it may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration at 2 to 8°C when not in use. The reconstituted vaccine can remain in storage between 2 to 8°C when not in use during those 30 days.

The package insert says the reconstituted vaccine should be stored for 15 days. Why is there a discrepancy?
Wyeth Pharmaceuticals, the manufacturer of Dryvax®, sent a letter to the attention of CDC stating that the FDA approved additional data that Wyeth submitted to support the storage of the reconstituted vaccine for 30 days at 2 to 8°C. This letter will accompany each kit of vaccine. Please note that the date of reconstitution should be recorded directly on the vaccine vial in the space provided. The letter can be viewed at www.bt.cdc.gov/agent/smallpox/vaccination/pdf/wyeth-dryvax-letter-dec-23-2002.pdf.

Can vaccine that has been reconstituted and used for 4 hours be refrigerated over night and then reused the next day?
Yes. Properly reconstituted and maintained Dryvax® vaccine can be stored and used for 30 days after being reconstituted. During that time it may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration at 2 to 8°C when not in use.

Do individuals who are involved in the packaging, shipping, general handling, or distribution of the smallpox vaccine need to be vaccinated themselves?
CDC only provides smallpox vaccine that has been properly packaged by companies with adequate manufacturing and production quality control or quality assurance standards in place. Because these quality control or assurance procedures ensure a properly packaged vaccine product, it is not necessary to vaccinate individuals who routinely package, ship, handle, or distribute small quantities of smallpox vaccine.

Can an individual, who has contraindications for receiving the smallpox vaccine, ship, handle, or distribute open vials of smallpox vaccine that may be returned from a clinic?
If proper packing and shipping procedures are observed in normal shipping activities, a person handling smallpox vaccine vials would not come into direct contact with the vaccine. Therefore, even if they have a contraindication to the vaccine, vaccine shippers should be able to handle the shipping, handling, and distribution of vaccine vials. However, if there is concern, the shipper can either use gloves when handling smallpox vaccine shipments or another person without contraindications to the vaccine should handle the vials, especially if there has been any damage to the vials in transit.

When is the new vaccine expected?
The production of new vaccine (Acam) is expected to be completed in May 2003. The vaccine is undergoing testing and licensure of this vaccine is expected to occur in early 2004.

Is the CDC recommending that only the bifurcated needle accompanying the vaccine vials be used?
Yes. The needle accompanying the vaccine in the vaccine kits is the only needle that has been licensed for use with this vaccine. No other needles are recommended for use with this vaccine.

Does the CDC see any problem with the use of the Univec safety (shielded) bifurcated needle?
This needle is not licensed for use with the smallpox vaccine. It has not yet been shown to be safer than the needle included with the vaccine.

What bifurcated needles can be used with the smallpox vaccine?
The Food and Drug Administration has approved a new 100-dose kit for the administration of Dryvax smallpox vaccine with Precision bifurcated needles. Only Precision bifurcated needles were included in the approved kit. Any change in the kit would require FDA review.

POST-EVENT

How do we expect a smallpox attack to occur, if one happens?

The deliberate release of smallpox as an epidemic disease is now regarded as a possibility. We can't say with certainty how an attack might occur, but we do know how smallpox is normally transmitted. Transmission most often occurs through person-to-person contact, more rarely through contact with materials contaminated with the smallpox virus, rarely through airborne contagion in enclosed settings. Because an attack could have such serious consequences, every effort is being made to prepare for such a possibility even though it is unlikely to ever occur. These preparedness efforts therefore include use of the best way to prevent smallpox: vaccination.

If a smallpox event were suspected to have occurred in a particular facility, what would be done to protect the employees?

If a smallpox event were suspected to have occurred in a facility, response plans are in place to try to document the presence of smallpox and rapidly initiate isolation procedures and vaccinate exposed persons if that is deemed appropriate. You can find out more about containment strategies in the Smallpox Response Plan and Guidelines in Guide A and Guide C.

What designates a smallpox emergency to initiate post-event plans?

Just one confirmed case of smallpox would be considered a public health emergency. The response would be rapid and designed to quickly control spread, isolation of cases, vaccination of all potential contacts, and broader vaccination as deemed appropriate after consideration of further spread or future releases of smallpox and after consultation with local, state, and federal authorities.

During a smallpox emergency, would children under 18 receive the vaccine?

During a smallpox emergency, all contraindications to vaccination would be reconsidered in the light of the risk of a smallpox exposure, and persons would be advised by public health authorities on recommendations for vaccination. Children between the ages of 12 months and 18 years would be eligible for vaccination. More information on vaccination strategies can be found in the Smallpox Response Plan and Guidelines Guide B.

Is the decision that there would be no contraindications during a smallpox emergency based on public health data or studies?

As with any public health intervention, we try to balance the risk of the intervention against the risk of the disease. During a smallpox bioterrorism event, the risk of disease would increase substantially and be sufficiently high to merit vaccination for many persons who should not be vaccinated now. However, the only situation that would lead to no (or nearly no) contraindications to vaccination is a direct, high-risk exposure to smallpox, such as would occur in a household with a person ill with smallpox case. This recommendation is based on extensive experience in the past that suggests that many people with these types of exposures will contract smallpox if not vaccinated.

Why are we even bringing smallpox patients to the hospitals? Why not just keep them at home where they've already exposed everyone?

With good infection control practices and rooms with the appropriate air handling features, we can treat patients in the hospital without risking transmission to other patients and staff. The appropriate care and management of smallpox patients will probably require hospitalization. For more information on isolation and quarantine measures, please see Smallpox Response Plan and Guidelines Guide C.

What kind of personal protective equipment (PPE, especially respiratory) would be necessary for dealing with a smallpox patient?
Airborne and contact isolation precautions should be followed. Please see "Guideline for Isolation Precautions in Hospitals" for further information.

How do federal programs fit into post-event activities?
All federal agencies would participate in activities as outlined in the Federal Response Plan Emergency Service Function 8. In most instances, the federal agencies would support state and local activities.

What is the recommended mode of disposal of dead bodies infected with smallpox?
This is currently under consideration.

What is the role of medical examiners in smallpox surveillance?
Medical examiners have a key role in all aspects of bioterrorism surveillance, acting as a key sentinel for suspicious deaths that might indicate the presence of a bioterrorist agent. Medical examiners are invited to work with their state health departments and/or bioterrorism programs on ways to become part of the effort. For more information, please visit the Medical Examiner and Coroner Information Sharing Program.

LABORATORY

Will Level A and B Laboratory staff be required to get vaccinated?
No. Level A and B laboratory staff will not be required to be vaccinated, but vaccination will be offered through the Laboratory Response Network. Generally, however, the amount of virus in specimens for routine clinical laboratory testing, and not virus diagnostic testing, would be low and good laboratory safety practices should protect laboratory staff from exposure. For more information on laboratory safety practices, please see the "Biosafety" section of the Public Health Emergency Preparedness and Response Laboratory Information page.

CONTRAINDICATIONS

Is there any particular risk for adverse reactions from people who wear contact lenses?
Vaccinia infection of the eye is a potentially serious complication of vaccination and can lead to altered vision. Therefore, all vaccinees need to be very careful to not inoculate the vaccinia into the eye. You should do several things to ensure you do not inoculate virus into your eye. Covering the vaccine site with gauze, tape, and a sleeved shirt or similar clothing, and careful handwashing decreases the chance of inadvertently getting vaccinia virus on your hands and possibly into your eye. Additionally, you should take extra care to wash your hands before handling your contact lenses.

Is a history of no adverse reactions in childhood to smallpox vaccine a predictor of no or minor reactions to revaccination in adulthood?
No. Simply because a person did not experience an adverse reaction to the vaccine in childhood does not mean that they will not experience adverse reactions as an adult. Many of the conditions that increase the likelihood of serious adverse reactions may not have been present in childhood (e.g., skin conditions, taking medication that suppresses the immune system).

Can clinic staff refuse to vaccinate someone with contraindications who insists upon being vaccinated despite risk/benefit information?
Clinic staff are not obligated to vaccinate persons who have valid contraindications.

If a person is being revaccinated, do the same contraindications apply?
Yes, smallpox vaccine contraindications are the same for first-time and revaccinations.

Is an inadvertently inoculated person considered immune?
Yes, an inadvertently inoculated person who develops a "take-like" reaction at the inoculation site should be considered immune.

In the webcast, "previous allergic reaction to vaccine" was listed as a contraindication to receiving a smallpox vaccination. Does this apply to reactions to other vaccines as well as the smallpox vaccine?
No, this only applies to smallpox vaccine or any of the smallpox vaccine's components including polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate.

What are the contraindications to revaccination or booster shots if there is an equivocal or negative "take"? E.g., erythema multiforme with or without urticaria to the primary or most recent vaccination?
The same contraindications that apply to primary vaccinations also apply to revaccinations following equivocal or negative takes.

I am allergic to eggs. Can I still get vaccinated against smallpox?
An egg allergy is not a contraindication to smallpox vaccination. Egg is not used in the manufacture of the vaccine.

Should healthcare providers who have contraindications to vaccination be excluded from evaluating and caring for people experiencing complications from vaccination?
No, they should not be excluded if they use proper infection control precautions.

There are contraindications for persons with eczema or atopic dermatitis to not be vaccinated. How are you defining eczema and do the contraindications include any type of eczema, either current or in the past?
Although eczema and atopic dermatitis are not the same disease, we recognize that many healthcare providers use the terms interchangeably. Because of that practice, the Advisory Committee on Immunization Practices felt that the risk that an individual with a valid contraindication (e.g., atopic dermatitis) might be inappropriately vaccinated was unacceptable. Thus, the committee elected to combine eczema and atopic dermatitis as a single contraindication. However, if the healthcare provider and patient are confident that the rash or diagnosis is not atopic dermatitis or eczema (being used as the label for actual atopic dermatitis), then the patient may be vaccinated provided there are no additional contraindications. An individual who has resolved eczematous rash (e.g., contact dermatitis) may be safely vaccinated because the contraindication would apply while the rash was in the active state.

My vaccination record shows that I had a "major reaction" to smallpox in the past, does that mean I should not get the vaccine? Am I at risk from the vaccine?
No. The term "major reaction" does not refer to a bad reaction to the vaccine, it is the terminology used to describe a successful vaccination. A "major reaction" means that virus replication took place and the person who received the vaccine is protected. Individuals who have had smallpox vaccine in the past and experienced "major reactions" are less likely to have side effects from the vaccine.

VACCINEE EVALUATION AND FOLLOW-UP

Can I share a bed after vaccination?

Special care must be taken following vaccination with the smallpox vaccine in order to avoid contact spread of vaccinia. If specific precautions are followed, then individuals who have been vaccinated can share a bed with others. These precautions are: The vaccination site must be covered with a gauze bandage held in place with medical tape. As an extra precaution, the vaccinated person should wear a t-shirt or pajamas that cover the vaccination site. If the individual who has been vaccinated is not following these precautions then it is better not to share a bed. These precautions must be followed until the scab that forms at the site of the vaccination falls off on its own (2 to 3 weeks).

How should bed linens and clothing that has been in contact with the vaccination site be handled?

Clothing or any other material that may have come in contact with the vaccination site and therefore be contaminated with vaccinia should be handled with special care. A separate hamper should be used for these items. Contact with these items should be kept to a minimum. These items should be laundered in warm water with detergent and/or bleach. After handling, individuals should wash their hands thoroughly in warm water with soap.

Can I prepare food for others while my vaccination site is "active"?

Individuals who have been vaccinated can cook and clean normally as long as they wash their hands after contact with the vaccination site or any potentially contaminated materials.

As a healthcare worker who has just been vaccinated, what is considered adequate hand washing? Can I use alcohol wipes?

Hands must be washed with soap and water after every contact with the vaccination site, the vaccine, or any material (clothing, dressing, etc…) that has come in contact with a vaccination site. Alcohol wipes may not clean thoroughly under the nails or over the entire surface area of the hand whereas good hand washing with soap and water will.

Can vaccinators immediately begin inoculating others after they've been vaccinated or should they wait a period of time and if so, how much time?

They can begin vaccinating others immediately. Vaccinators are vaccinated in part to assure that they have been screened to receive vaccine, so that someone who has a contraindication is not administering vaccine and taking the chance that they are accidentally exposed. Vaccinators need to remember that they too may experience fever, fatigue and other side effects as well as robust reactions at the site. If they wait to be vaccinated until they begin work immunizing others, they may not feel well enough and will need to deal with the reaction sites in the midst of the vaccination clinics. Consequently, while it is not mandatory, it may be better to try to vaccinate the clinic's staff 2 or 3 weeks before the clinics are scheduled to open.

Do healthcare workers who have been vaccinated need to wear masks when working with immunocompromised patients?

No. Vaccinia, the live virus in the smallpox vaccine, is spread by touch. Vaccinia has not been shown to spread through airborne contagion.

Can a person travel outside of the country after being vaccinated? How soon?
There are no restrictions on travel following vaccination. However, you may not feel like traveling for a few days after getting the vaccine (usually about a week or so after vaccination). Most people experience normal, usually mild reactions that include a sore arm, fever and body aches. In recent tests, one in three people felt bad enough to miss work, school, a recreational activity, or had trouble sleeping after getting the vaccine.

Can someone who recently has been vaccinated swim in a public pool?
The vaccination site should be kept dry at all times. A water-resistant pad, such as a waterproof band-aid is required for showering. It would be difficult to keep the vaccination site dry during swimming. It is probably wise not to swim.

EVALUATION, MANAGEMENT, AND TREATMENT OF ADVERSE EVENTS

What is the planned antiviral prophylaxis for vaccinia/smallpox?
There currently are no protocols for antiviral prophylaxis for vaccinia or smallpox, only treatment protocols.

What should I do if I were to accidentally get some of the reconstituted smallpox vaccine in my eye?
If someone accidentally gets vaccinia in their eye, via contact with a glove, hand or a splash, they should flush the eye completely with water, as well as wash their face. Baseline evaluation by an ophthalmologist may be considered but is not necessary. Should vaccinia lesions develop in the ocular area, including the eyelids, further evaluation will be necessary.

OTHER QUESTIONS ABOUT THE VACCINE

Does the smallpox vaccine that will be used today contain a live virus? Did previous vaccines use live viruses as well?
The smallpox vaccine that will be used does contain a live virus: vaccinia virus. Throughout the history of smallpox vaccination, a strain of live virus has been used. These viruses have been from the Orthopox genus of viruses that contains smallpox virus (variola), cowpox, monkeypox, camelpox, and some other viruses.

Edward Jenner, who in 1796 introduced the practice of causing an infection with a different but related virus as a means to protect against smallpox, is believed to have used the cowpox virus. Over time, the species of Orthopoxvirus used to make vaccines shifted to vaccinia. The vaccinia strain has been used in recent times and helped accomplish the eradication of natural smallpox.

Was cowpox ever used to treat smallpox? Could we use it today?
The Orthopoxviruses were used to make vaccines and not to treat a case of the disease.

Why is the old Dryvax® vaccine being used instead of new vaccine?
Right now, the United States has two supplies of smallpox vaccine: 15 million doses of Dryvax® and 85 million doses of Aventis Pasteur. Dilution studies have indicated that these 100 million doses could be safely and effectively diluted by 5, resulting in 500 million doses of vaccine, enough for every American. At the moment, however, only two lots of the Dryvax® vaccine (2.7 million doses) are approved for distribution as a licensed vaccine. One million doses are designated for the Department of Defense. The remaining 1.7 million doses are designated for the Department of Health and Human Services. This vaccine will be used as part of the smallpox preparedness vaccination activities. While new vaccine is under production, this will not be available until May of 2003 and it would still need to be licensed. Dryvax® has been used extensively and shown to be safe and effective in most people.

Many of us received smallpox vaccinations years ago and don't recall hearing of risks involved or serious consequences occurring. Why are there so many problems with side effects now?
Even though you don't recall hearing about problems in past years, there were some, according to the Centers for Disease Control and Prevention. The side effects aren't anything new. About 1,000 people for every 1 million people vaccinated for the first time experienced reactions that, while not life-threatening, were serious. These included a vigorous (toxic or allergic) reaction at the site of the vaccination and spread of the vaccinia virus (the live virus in the smallpox vaccine) to other parts of the body and to other people. Although it has been rare, CDC reports that many people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million vaccinated experienced potentially life-threatening reactions. Additionally, based on past experience, it is estimated that between 1 and 2 people out of every 1 million people vaccinated *may* die as a result of life-threatening reactions to the vaccine. Please see our online information at www.bt.cdc.gov/agent/smallpox/overview/faq.asp.

Does the smallpox vaccine contain thimerosal?
The current formulation of smallpox vaccine does not contain thimerosal.

Is the vaccine being administered to members of healthcare response teams full-strength or diluted?
The vaccine to be used for smallpox response teams is full-strength dried calf lymph type Dryvax vaccine. It is licensed and passes all tests required by the Food and Drug Administration.

Will the vaccine be diluted?
While dilution studies have shown that both Dryvax and Aventis Pasteur vaccine supplies could be diluted by 5 and still retain their efficacy, there are no plans to routinely dilute smallpox vaccine. Existing supplies of smallpox vaccine would only be diluted in the event of an emergency. New supplies of smallpox vaccine (Acam) are being produced and are expected to be licensed in early 2004. This is the vaccine that would be used for more wider application among the American public should the decision be made to provide the vaccine to the public.